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Research Article

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Analysis of Antibiotics (Amoxicillin) and Anti-Hypertensive (Nifedipine) Drugs

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Abstract This work analyzed ten capsules of amocycillin 500 mg each from drug resolving stores (shop 1), Opaclsas Pharmacy (shop 2), Happy Home Pharmacy (shop 3), Cheff Pharmacy Ltd (shop 4) Chimezie Medicine Stores (shop 5). The anti-hypertensive drugs (Nifedipine, 20 mg) were obtained from drug resolving stores (shop 1), Happy Home Pharmacy (shop 2), Cheff Pharmacy (shop 3), Chimezie Medicine stores (shop 4) and D-Global Pharmacy (shop 5). All capsules and tablets were obtained from different locations in Asaba. The analysis carried out on them are disintegration time, percentage uniformity of weight and percentage active ingredients they contain. The disintegration time for amoxicillin obtained from shop 1, shop 2, shop 3, shop 4 and shop 5 are: 11 minutes, 7 minutes, 8 minutes, 9 minutes and 10 minutes respectively. The percentage uniformity of weight for the five amoxicillin are 100 % each. The percentage active ingredients were found to be 104.9 %, 108.1 %, 109.98 %, 103.2 % and 109.3 % respectively. The disintegration time, percentage uniformity of weight and percentage active ingredients conformed to British pharmacopeia specifications. The disintegration time for the five antihypertensive drugs were found to be: 120 minutes, 20 seconds, 18 seconds, 25 seconds and 20 seconds respectively. The percentage uniformity of weight for the five antihypertensive drugs are 100 % each. The percentage active ingredients for them are 102.5 %, 95.4 %, 107.6 %, 101.5 % and 92.8 % respectively. Again, the disintegration time, percentage uniformity of weight and percentage active ingredients, all conformed to B.P. specification.

Keywords Amoxycillin 500mg, Nifedipine 20mg, disintegration time, percentage uniformity of weight, percentage active ingredients and B.P. specification

Introduction

Antibiotics or antibacteria are type of antimicrobia used specifically against bacteria and are often used in medical treatment of bacterial infections. They may either kill or inhibit the growth of bacteria. Several antibiotics are also effective against a number of fungi, protozoa and some are toxic to humans and animals, even when given in therapeutic dosage. Antibiotics are not influenza, and may be harmful when taken inappropriately.

With advances in medical chemistry, most modern antibacteria are semi synthetic modification of various natural compounds. These include, for example, the beta-lactum antibiotics, which include the penicillins (produced by fungi in the genus penicillium), the isolated from living organisms are the aminoglycosides, whereas other antibacteria for examples, the sulfonamides, the quinoes, and the oxazolidinones with this, many anti-bacterial compounds are classified on the basis of chemical/biosynthetic origin into natural, semi synthetic and synthetic [1]. Another classification system is based on biological activity, in this classification; antibacteria are divided into broad groups according to their biological effect on micro-organisms. Bactericidal agent kill bacteria and bacteriostatic agent slow down or stall bacterial growth. Antibiotics are screened for any negative effects on humans or other mammals before approval for clinical use, and are usually considered safe and most are well-tolerated. However, some antibiotics have been associated with a range of adverse side effects. Some scientists have hypothesized that

the use of antibiotics alter the host microbiota and this have been associated with chronic disease [2]. Clinicians have recommended that extra contraceptive measures be applied during therapies using antibacterial that are suspected to interact with oral contraceptive [3].

The emergence of resistance of bacteria to antibiotic is a common phenomenon. Antibiotic such as penicillin and erythromycin, which use to have a high efficacy against many bacterial species and strains, have become less effective, due to the increased resistance of many bacterial strains [4]. Inappropriate antibiotic treatment and over use of antibiotics have contributed to the emergence of antibiotic resistant bacteria. Self prescription of antibiotics is an example of misuse.

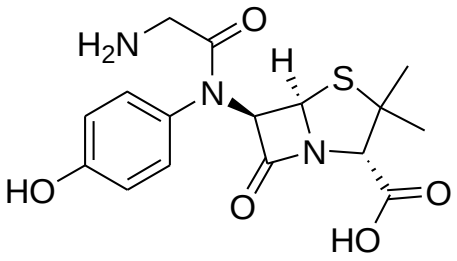
Interactions between alcohol and certain antibiotics may occur and may cause side-effects and decreased effectiveness of antibiotic therapy. "It is sensible to avoid drinking alcohol when taking medication. However, it is unlikely that drinking, alcohol in moderation will cause problems if you are taking most common antibiotics. However, there are specific types of antibiotic with which alcohol should be avoided completely, because of serious side-effects" [5]. Therefore, potential risk of side-effects and effectiveness depend on the type of antibiotic administered. Despite the lack of categorical counter indication, the belief that alcohol and antibiotics should never be mixed is widespread [6]. Antibiotics such as mefronidazole, tinizole, cephamandole, latamoxef, cefoerazone, cefmenoxime and furazolidone cause a disulfiram-like chemical reaction with alcohol by inhibiting its break down by acetaldehyde dehydrogenase which may result in vomiting, nausea, and shortness of breath. Other effects of alcohol on antibiotic include altering activity of the liver enzymes that break down the antibiotic compound [7].

Antihypertensives are a class of drugs that are used to treat hypertension (high blood pressure). Antihypertensive therapy seeks to prevent the complications of high blood pressure, such as stroke, myocardial infarction, ischaemic heart disease, heart failure and cardiovascular disease. Many classes of antihypertensive, which help to lower blood pressure by different means include: thiazida diuretics, calcium channels blockers, ACE inhibitors anglotensin II receptor antagonists and beta blockers [8]. An ACE inhibitor is recommended by NICE in Uk for those under 55 years old [9].

The aims and objectives of this work are:

- To analyze the disintegration time, percentage uniformity of weight and percentage active ingredients in ten amoxicillin capsules (500 mg) obtained from each of the five shops situated at different locations in Asaba.
- To analyze the disintegration time, percentage uniformity of weight and percentage active ingredients in ten antihypertensive (nifedipine 20 mg) drugs selected from each of the five shops situated at different locations in Asaba
- To ascertain the quality of drugs dispensed to the public by comparing the findings with B.P. specification.

Methodology (Analysis of Antibiotics)



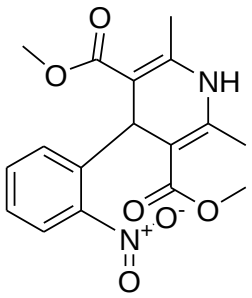
Amoxycillintrihydrate is (6R)-6-(α-D-4-hydroxyphenylglycyl-amino) penicillanic acid trihydrate.

Determination of percentage active ingredient in the drug

Equivalent of 125 mg was weighed into a 50 ml volumetric flask. 1 ml of the resulting solution was added to 50 ml volumetric flask and made up to mark with 0.1 M NaOH. Absorbance reading was taken at wavelength of 292 nm using the spectrophotometer.

Determination of disintegration time

The medium is introduced into the sample compartment to 700 ml mark on the beaker. The heater is switched on to condition the water to 36.5 °C at this temperature of 36.5 °C, the tablets are placed in the rigid basket rack assembly. The time taken for the drug to disintegrate is recorded [10].



Nifedipine is dimethyl 1,4-dihydro-2, 6-dimethyl-4-(2-nitrophenyl) phyridine-3,5-dicarboxylate

Determination of percentage active ingredients in the drug

Equivalent of 10 mg of the drug weighed into 50 ml volumetric flask. It was dissolved with methanol and made up to mark with methanol. The solution was filtered and 5 ml of the filtrate was taken into 25 ml flask. The absorbance reading at 355 nm was taken using the spectrophotometer.

Determination of disintegration time

The medium is introduced into the 100 ml beaker and made up to 700 ml mark. The heater is switched on to condition the water to a temperature of 36.5 ^{o}C is at this temperature of 36.5 ^{o}C, the tablets are placed in the rigid basket rack assembly. The time taken for the drug to disintegrate is recorded [10].

Results and Discussion

Amoxycillin (Lamax 500 mg) Drug Resolving Store (shop 1)

Manufacturing Date:	May, 2014
Expiring Date:	April, 2016
NAFDAC NO:	Lam 926
Manufacturer:	Me Cure Ind. Ltd. Lagos
Description:	Red and yellow capsule with lamox written on one side and 500mg written on the yellow side.

Amoxycillin (Emmox 500 mg) Operclass Pharmacy (shop 2)

Manufacturing Date:	March, 2015
Expiring Date:	March, 2018
NAFDAC NO:	04-5728
Manufacturer:	Emzor Pharm Lagos
Description:	Red and yellow capsule with Emzor and 500mg written on the yellow side.

Amoxycillin (Moxitin 500mg) Happy Home Pharm. (shop 3)

Manufacturing Date:	July, 2014
Expiring Date:	July, 2017
NAFDAC NO:	04-4800
Manufacturer:	Clarin Medical; Lagos
Description:	Red and yellow capsule with 500 MXTN written on the yellow side.

Amoxycillin (Florimox 500mg) Cheff Pharm. (shop 4)

Manufacturing Date:	March, 2014
Expiring Date:	February, 2017

Batch No: 4005
NAFDAC NO: A4-0701
Manufacturer: Clarin Medical; Lagos
Description: Red and yellow capsule with florimox on the red side and even on the yellow side.

Amoxycillin (DrAmoxycillin 500mg) Chimezie Medicines (shop 5)
Manufacturing Date: April, 2014
Expiring Date: April, 2018
Batch No: 123080
Description: Red and yellow capsule Dramoxycillin 500mg on the yellow side and DGF on the other sides.

NifedipineCalcicor 20mg, Drug Revolving stores (shop 1)
Manufacturing Date: June, 2012
Batch No: 52006
Expiring Date: April, 2016
Manufacturer: Remedial Ltd., Cyprus
Description: A round, pink-grey colour, enteric coated tablet with N on one side and nothing on the other side.

NifedipineDexcel 20mg, Happy Home Pharm (shop 2)
Manufacturing Date: January, 2014
Expiring Date: January, 2017
NAFDAC No: 04-4499
Manufacturer: A Dexon Company, Israel
Description: Round film coated pink table with Dx on one side, nothing on the other side

NifedipineDexcel 20mg, Cheff Pharmacy (shop 3)
Manufacturing Date: January, 2014
Expiring Date: January, 2017
NAFDAC No: 04-4499
Manufacturer: Dexcel Ltd., ADexon Company, Israel
Description: Round film coated pink table with Dx on one side, nothing on the other side
NifedipineDexcel 20mg, ChimezieMedcine (shop 4)
Manufacturing Date: January, 2014
Expiring Date: January, 2017
NAFDAC No: 04-4499
Manufacturer: A Dexon Company, Israel
Description: Round film coated pink table with Dx on one side, nothing on the other side
NifedipineDexcel 20mg, D-Global Pharmacy (shop 5)
Manufacturing Date: January, 2014
Expiring Date: January, 2017
NAFDAC No: 04-4499
Manufacturer: A Dexon Company, Israel
Description: Round film coated pink table with Dx on one side, nothing on the other side

Table 1: Weight of 10 capsules of amoxycillin 500mg (in g) from different locations in Asaba

S/No	Shop 1 Lamoxamoxycillin	Shop 2 Emmoxamoxycillin	Shop 3 Moxitinamoxycilin	Shop 4 Florimoxamoxycilin	Shop 5 Dramoxycillinamoxycillin
1	0.568	0.577	0.599	0.584	0.594
2	0.571	0.598	0.590	0.586	0.618
3	0.614	0.614	0.594	0.600	0.592
4	0.602	0.584	0.587	0.584	0.608
5	0.588	0.604	0.561	0.591	0.597
6	0.573	0.612	0.610	0.578	0.627
7	0.587	0.585	0.594	0.579	0.611
8	0.596	0.601	.982	0.590	0.617
9	0.583	0.588	0.582	0.587	0.571
10	0.586	0.581	0.593	0.586	0.618
Total	5.868g	5.942g	5.912g	5.865g	6.053g
Average	0.587g	0.594g	0.591g	0.587g	0.605g

Table 2: Weight of 10 tablets of Nifediphine 20mg (in g) from different locations in Asaba

S/No	Shop 1 CalcicorNifedipine	Shop 2 DexcelNifedipine	Shop 3 DexcelNifedipine	Shop 4 DexcelNifedipine	Shop 5 DexcelNifedipine
1	0.090	0.210	0.205	0.213	0.211
2	0.089	0.213	0.209	0.208	0.210
3	0.089	0.213	0.205	0.212	0.214
4	0.089	0.212	0.211	0.208	0.211
5	0.088	0.213	0.209	0.209	0.211
6	0.090	0.209	0.208	0.211	0.211
7	0.088	0.21	0.210	0.215	0.211
8	0.086	0.213	0.208	0.210	0.210
9	0.088	0.213	0.210	0.211	0.214
10	0.089	0.213	0.210	0.210	0.206
Total	0.886g	2.117g	2.090g	2.106g	2.11g
Average	0.089g	0.212g	0.201g	0.211g	0.211g

Table 3: Disintegration time, percentage uniformity of weight and percentage active ingredients of amoxycillins (antibiotics)

Amoxycillin 500mg	Shop1 drug resolving stores opposite Okocha Motors, Summit Junction, Asaba	Shop 2 Opaclass Pharm Ltd. Core area phase II, Asaba	Shop 3 Happy home Pharm. Ltd, Okutegbu Quarters Asaba	Shop 4 Cheff Pharm., Opposite Legislature quarters Asaba	Shop 5 Chimezie Medicine stores opposite fine gate, Asaba	British Pharmacopoeia specifications
Disintegration time	11 minutes	7 minutes	8 minutes	9 minutes	10 minutes	30 minutes
Percentage uniformity of weight	100%	100%	100%	100%	100%	92.5%-107.50%
Percentage active ingredients	104.9%	108.1%	109.98%	103.2%	109.3%	90.0%-110.0%

Table 4: Disintegration time, percentage uniformity of weight and percentage active ingredients of Nifedipine

Nifedipine	Shop 1drug resoling stores opposite Okocha Motors, Summit Junction, Asaba	Shop 2 Opaclass Pharm Ltd. Core area phase II, Asaba	Shop 3 Happy home Pharm. Ltd, Okutegbu Quarters Asaba	Shop 4 Cheff Pharm., Opposite Legislature quarters Asaba	Shop 5 Chimezie Medicine stores opposite fine gate, Asaba	British Pharmacopoeia specifications
Disintegration time	120 minutes	20 minutes	18 minutes	25 minutes	10 minutes	30 minutes
Percentage uniformity of weight	100%	100%	100%	100%	100%	90.0%-110.0%
Percentage active ingredients	102.5%	95.4%	107.6%	101.5%	92.8%	90.0%-110.0%

Table 1 showed the weight of ten capsules of amoxycillin (500mg) obtained from each of the five shops situated at different locations in Asaba. The weight of the ten capsule obtained from each shop is similar and comparable to one another. Again the average weight of the ten capsules selected from shop 1 is also similar and comparable to the average weight of the ten capsules collected from shops 2-5. The average weight of the ten capsules got from shops 1- 5 are: 0.587g, 0.594g, 0.597g, 0.587g and 0.605g respectively. One can therefore say at a glance that there is no significant difference between the average weight of the ten amoxycillin capsules selected from each of the shops. Table 2 potrayed the weight of ten tablets of nifedipine (20mg) obtained from each of the five shops situated at different locations in Asaba. The average weight of the ten tablets selected from shop 1 is 0.089g. It is not very comparable to the average weight of the ten tablets collected from shops 2- 5. The average weight are: 0.212g, 0.201g, 0.211g and 0.211g respectively. This may be as a result of the fact that they are from two different manufacturers. Nifedipine tablets from shop 1 is manufactured by Calcicor while the ones from shops 2 -5 are manufactured by Dexcel.

Table 3 signified the different location of shops 1- 5 in Asaba environs. It also pointed out the disintegration time, percentage uniformity of weight and percentage active ingredients of different amoxycilling, capsules. For active ingredient to start working in the body, it must first of all be broken up (disintegrated) or digested unto smaller absorbable form. The smaller absorbable forms will then diffuse into the blood stream through the walls of the intestine. The blood will then carry the active ingredients to the cells of the body where they do the work of killing the disease causing micro-organisms (bacteria, fungi, virus etc). So the smaller the disintegration time, the faster the rate of diffusion of the active ingredients into the blood stream and the faster the rate at which diseases can be addressed. The drug with the fastest rate of disintegration is the amoxycillin from shop 2. The increasing order of the disintegration time of these drugs is as follows: drug from shop 2 < drug from shop 3 < drug from shop 4 < drug from shop 5 < drug from shop 1. The corresponding values are as follows: 7 mins< 8 mins< 9 mins< 10 mins< 11 mins respectively.

The results of disintegration time, percentage uniformity of weight and percentage active ingredients obtained are in conformity to British pharmacopeic specifications. For one not to take under dose or over dose of a drug, the weight of the drugs must be uniform. Drug that is show gross deviation from stated content are not in conformity to standard specifications**.** This can affect the active ingredient content in each tablet or capsule. Hence quality control measures must be put in place to ensure that drugs produced meet B.P. specifications. Equipments must be maintained periodically so that results from such equipment can be absolutely reliable and in compliance with international standards. Table 4 exposed the disintegration time, percentage uniformity and weight and percentage active ingredients of Nifedipine 20 mg. The three parameters complied with B.P. specification. Weight variations affect accurate prescription.

Conclusion and Recommendation

Different amoxycillin (500 mg) capsules and nifedipine (20 mg) analyzed meet British Pharmacopeia specifications or requirements. Drug weight must be uniform size. For this to be achieved, good tabulating machines should be used. There should be periodic maintenance of equipment in order to obtain quality products. Standard procedures must be followed. Deviation from standard procedures will lead to substandard products which is not healthy for the populace. Weight variation can affect the active ingredients; hence weight of drugs must be uniform. The coating materials must comply with standard specification so that drugs can breakdown with ease. Quality drugs are obtained through good quality control and quality assessment of the entire systems. Good equipment, quality control laboratory and trained personnel will go a long way in producing products that will meet local, national and international standards.

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